K041781

MAR 1 4 2005

9 510(K) SUMMARY

1. **Summary Preparation Date:** January 18, 2005

2. **Applicant Information:**

Name: Hamilton Medical AG
Via Nova
CH-7403 Rhäzüns
Switzerland
FDA Establishmen Registration Number: 3001421318
Contact Person:J.. David Thompson, General Manager
Hamilton Medical Inc.
P.O.Box 30008
Reno, NV 89502
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Email: thompson@hammed1.com

3. **Device Proprietary Name:** VENTILAIR II Medical Air Compressor

Common/Usual Name: Air Compressor
Classification Name: Compressor, Air, Portable
Classification Panel: Anesthesiology
Classification Code: BTI

4. **BTI Device Identification Code** (per 21 SFR Part 868.6250): A portable air compressor is a device to provide comopressed air for medical purposes, e.g. to drive ventilators and other respiratory devices.

5. **Regulatory Status:** Portable air compressors and their accessories (FDA product code BTI) have been classified by the FDA as class II. There are currently no mandatory performance standards or special control requirements for these devices.

6. **Intended Use:** The Hamilton Medical VENTILAIR II is intended for use in hospitals and other institutions as an alternative to central air or cylinder air to supply medical air at 30 psi nominal to the GALILEO and the RAPHAEL models of Hamilton Medical ventilators which are intended to be operated with 30 psi nominal medical air supply. It can also be used as a backup medical air supply for these ventilators in case of failure of their normal air supply.

7. **General Device Description:** The VENTILAIR II is an electromechanical and pneumatic device only and has no software-based components. The device is rated at 115 V ± 10 %, 60 Hertz. It requires 466 Watts to power. The enclosure is designed to be mounted either on the GALILEO model or RAPHAEL model ventilator carts.

Only one control is accessed during normal device operation, a power switch. The Power switch is switched ON both when the VENTILAIR II is configured and operated as a permanent air supply and when it is used as an emergency backup air supply. An indicator is provided to inform the user of the device performance status. This "Performance Gauge" is a pressure gauge calibrated for three zones of operation: Green (Normal Dry Operation), Yellow (Poor Drying Effect), and Red (Wet with Low Output Pressure).

The VENTILAIR II has two air movements. The first is the cool, clean, dry compressed air movement that provides condensation-free compressed air to the ventilator. The second is the ambient air movement – an S-pattern that cools the entire drying system and compressor within the enclosure.

The VENTILAIR II has been designed for easy maintenance. The compressor air intake filter element must be checked weekly. The 5 micron filter in the water trap must be replaced annually. Two internal pressure regulators and two other internal components must be checked annually and adjusted if necessary. Compressor overhaul is required periodically using the compressor manufacturer's overhaul kit. If the VENTILAIR II is used as an independent or continuous air source, an annual overhaul is recommended. If the compressor is used only as a backup in case of failure of the main air supply, overhaul is recommended every five years. All maintenance and overhaul procedures are described in detail in the VENTILAIR II Operator's and Service Manuals.

The VENTILAIR II is in full compliance with all required safety aspects of the current edition of IEC 60601-1. Several specific safety mechanisms have been incorporated into the VENTILAIR II.

8. **Device Materials:** All materials within the VENTILAIR II flow path have been carefully selected to avoid any contamination of the medical air flow path. There are no plastic mold release compounds and no outgassed toxic material present to contaminate the gas flow. A 5 micron filter has been built into the device to capture any particulate impurities. In addition all Hamilton Medical GALILEO and RAPHAEL ventilators have a 0.5 micron filter built into their air inputs to trap any particulate impurities.

9. **Substanital Eqiuvalence:** The Hamilton Medical VENTILAIR II Medical Air Compressor is substantially equivalent to the Draeger Medical Air Compressor (K982789), Infrasonics Air Star Portable Compressor (K920954), and the Bennett MC-2 Mobile Air Compresor (Pre-Amendment).

   Among the information presented in the 510(k) submission to support the equivalency of the VENTILAIR II to these predicate devices is: (a.) device description, (b.) comparison to the legally marketed predicate devices, and (c.) laboratory performance verification and validation test data.

10. Comparison Table: The table that follows describes some Important characteristics of the VENTILAIR II Medical Air Compressor and its predicate devices: Draeger Medical Air Compressor (K982789), Infrasonics Air Star Portable Compressor (K920954), and Bennett MC-2 Mobile Air Compressor (Pre-Amendment).

Comparison to Legally Marketed Predicate Devices

		PREDICATE DEVICES			VENTILAIR II
#	**Characteristic**	**Bennett MC-2 Air Compressor (Pre-Amendment)**	**Draeger Medical Air Compressor (K982789)**	**Infrasonics Air Star Compressor (K920954)**	**Similar or Different (From All Other Predicates Combined)**
1	Intended use and applications	Source of compressed air for Bennet IPPB therapy units, respiration units and other devices requiring clean filtered air	Independent or backup compressed air source to power medical ICU ventilators	Independent or backup compressed air source to power Infrasonics Infant Star and other ventilators	Independent/backup 30 psi compressed air source to power GALILEO and RAPHAEL ventilators in hospitals and other institutions at 30 psi nominal operating pressure
2	User controls/visual indicators	Power switch / pressure gauge	Power switch / power LED, high air temperature LED	Power switch / pressure gauge, power LED, low pressure LED, compressor on LED and wall air on LED	Power switch / pressure performance gauge, power failure and low pressure indicators built into ventilator
3	Alarms	Audible and visual power failure and low pressure built into ventilator (respiration unit)	Audible and visual high output air temperature	Audible and visual power failure and low pressure	Audible and visual power failure and low pressure indicators built into ventilator
4	Filtering	Pre-compression HEPA filter; water trap filter (size unspecified in available labeling)	≤ 1 micron	Degree of filtering unspecified in available labeling	≤ 5 microns at output of device; 0.5 micron filter built into ventilator input
5	Water trap	Yes, with automatic vaporization	Yes, with automatic vaporization	Yes, with automatic vaporization	Yes, with automatic vaporization
6	Pressure relief valve	Yes, set to 60 PSIG	Yes, set to 59 PSIG	Yes, set to 85 PSIG	Yes, set to 32 PSIG
7	Auto backup pressure	Feature not available	On at 40.5 PSIG, off at 50 PSIG	Optional featue, on at 45 PSIG, off at 55 PSIG	On at 30 PSIG, off at 38 PSIG

		PREDICATE DEVICES			VENTILAIR II
#	Characteristic	Bennett MC-2 Air Compressor (Pre-Amendment)	Draeger Medical Air Compressor (K982789)	Infrasonics Air Star Compressor (K920954)	Similar or Different (From All Other Predicates Combined)
8	Electrical ratings	115 V; 60 Hertz; power consumption unspecified in available labeling	110 V; 60 Hertz; 500 W	102 to 132 V; 60 Hertz; power consumption unspecified in available labeling	115 ± 10 %; 60 Hertz; 466 W
9	Overcurrent protection	Unspecified in available labeling	Fuse	Circuit breaker	Fuse
10	Output	45 l/min at 50 PSIG	30 l/min at 44 PSIG	55 l/min at 50 PSIG	40 l/min at 30 PSIG
11	Dew point depression	Unspecified in available labeling	5 °C below room temperature at 30 l/min	> 3 °F below room temperature at 55 l/min	3.3 °C below room temperture at 40 l/min
12	Input/output interface	Two DISS $^{9}/_{16}$" – 18 threaded outlets (one capped when not in use)	Quick connect DISS coupling with internal check valve (1 input, 1 output)	¾ " – 16 male DISS fitting with internal check valve (optional input, 1 output)	¾" – 16 male DISS fitting with internal check valve (1 input, 1 output)
13	Ambient environment	Unspecified in available labeling	50 to 104 °F; 30 to 95 % RH, 13,000 ft max. altitude	20 to 95 °F; ≤ 99 % noncondensing RH; altitude unspecified in available labeling	50 to 104 °F; < 85 % RH; 7,200 ft maximum altitude
14	Noise level	Unspecified in available labeling	46 to 49 dB(A)	< 55 dB(A)	< 50 dB(A)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2005

Hamilton Medical AG
C/O Mr. J. David Thompson
General Manager
Hamilton Medical, Incorporated
P.O. Box 30008
Reno, Nevada 89502

Re: K041781
Trade/Device Name: Hamilton Medical VENTILAIR II Medical Air Compressor
Regulation Number: 868.6250
Regulation Name: Portable Air Compressor
Regulatory Class: II
Product Code: BTI
Dated: January 27, 2005
Received: January 28, 2005

Dear Mr. Thompson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

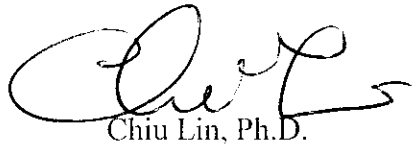
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1 INDICATION FOR USE STATEMENT

510(k) Number (if known) K041781

Device Name: Hamilton Medical VENTILAIR II Medical Air Compressor

Indications For Use:

The Hamilton Medical VENTILAIR II is intended for use in hospitals and other institutions as an alternative to central air or cylinder air to supply medical air at 30 psi nominal to the GALILEO and the RAPHAEL models of Hamilton Medical ventilators which are intended to be operated with 30 psi nominal medical air supply. It can also be used as a backup medical air supply for these ventilators in case of failure of their normal air supply.

Prescription Use: X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sign-Off)
...n of Anesthesiology, General Hospital,
...tion Control, Dental Devices
...) Number: K041781